

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 2/28/11 wherein claims 1-13 and 15 were canceled and claim 14 was amended.

Note: Claims 14 and 16-23 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/11 has been entered.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments and/or amendment filed 2/28/11 to the rejection of claims 14-23 made by the Examiner under 35 USC 112 first and second paragraph have been fully considered and deemed persuasive for the following reasons.

112 First Paragraph Rejection

The rejection is WITHDRAWN for reasons set forth in Applicant's response filed 2/28/11.

112 Second Paragraph Rejections

I. The 112 second paragraph rejection of claims 14-23 (as it related to the reaction by products of the mixture) is WITHDRAWN because Applicant amended the claims to overcome the rejection.

II. The 112 second paragraph rejection of claims 14-23 (as it relate to the radiolabeled products being referenced) is WITHDRAWN for reasons of record in Applicant's response.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejection

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14 and 16-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to what functional group is being references in Formula I and what 'radiolabeled portion' Applicant is

referring to that in the definition of R* of Formula III. Specifically, review of the specification does not identify the 'portion' of a structure/substance that Applicant is referring to in Formula III. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 Second Paragraph Rejections

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 14 and 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 16-23: Independent claim 14, line 22, as written is ambiguous because it is unclear what 'functional group' Applicant is referring to in Formula I. In addition, it is unclear what 'radiolabeled portion' Applicant is referring to. Specifically, a 'portion' of what substance is radiolabeled. Since claims 16-23 depend from claim 14, those claims are also vague and indefinite.

Claim 14, line 17: Claim 14 recites the limitation "said compound" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claims 22 and 23 recite the limitation "said reaction by-product" in lines 1-2 and 5 (claim 22) and 2 (claim 23). There is insufficient antecedent basis for this limitation in the claim.

COMMENTS/NOTES

8. It should be noted that no prior art has been cited against the instant invention. However, Applicant MUST address and overcome the 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a process of purifying a radiolabeled product as set forth in independent claim 14.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

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